K110119

JUN 10 2011

Attachment B
510(k) Summary of Safety and Effectiveness

Applicant:

NeoForce Group Inc
35 Commerce Drive
Ivyland, Pa 18974
Registration Number: 3005599562

Contact Person:

Monica Ferrante
VP Regulatory
Ph 215-672-6800
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Device trade/proprietary name:

NF-009 Pressure Manometer

Device common/usual/classification name:

Airway Pressure Monitor

Classification:

Anesthesiology
21 CFR 868.2600
Airway Pressure Monitor, CAP, Class II

Performance Standards:

None applicable

Predicate Device:

Pre-Amendment Pressure Manometer Anesthesia Associates Inc.
K954486 Mercury Medical Disposable Color Coded Manometer
K040991 Ambu Inc. Disposable Pressure Manometer
K072021 NeoPIP Infant Resuscitation Device
K092085 Ispira Resuscitation System
K102649 NeoPIP Infant Resuscitator with Flow meter

Device Description

The NF-009 Pressure Manometer is a low pressure gauge with a range of -20 to 80 cmH2O in marked increments of 1 cm H2O. The gauge has color coding green, yellow and red. The Manometer provides visual indication of airway pressure during ventilation or resuscitation.

Intended Use

The Pressure Manometer is used to provide visual indication of patient's airway pressure during ventilation. It may be attached by flexible tubing to devices providing expiratory pressure such as resuscitation bags, hyperinflation bags, CPAP Masks or Circuits.

Performance Data

The NF-009 Pressure Manometer performs equivalently to the test devices and is within the accuracy information specified for the predicate devices over the operational range. The accuracy for the predicate devices is shown in the comparison table with the worst case values +/-3 cm H2O for measurements less than 15 cm H2O and +/- 5 cm H2O greater than 15 cm H2O. The NF-009 is within 1 cm H2O of the Reference Gauge and the Digital Gauge.

The Performance Data demonstrate equivalence to the predicated devices.

Substantial Equivalence

The NF-009 Pressure Manometer is believed to be substantially equivalent to currently marketed pressure manometer devices with regards to intended use, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Monica Ferrante
VP Regulatory
NeoForce Group, Incorporated
35 Commerce Drive
Ivyland, Pennsylvania 18974

JUN 10 2011

Re: K110119
Trade/Device Name: Pressure Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: May 23, 2011
Received: May 23, 2011

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Indication for Use Statement

510(k) Number:

Device Name: Pressure Manometer

Indications for Use:

The Pressure Manometer is used to provide visual indication of patient's airway pressure during ventilation. It may be attached by flexible tubing to devices providing expiratory pressure such as resuscitation bags, hyperinflation bags, CPAP Masks or Circuits.

(Please do not write below this line continue on another page if needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110119